

II. Rejection under 35 U.S.C. § 102(b)

Claims 1-2 and 9-22 were rejected under 35 U.S.C. § 102(b) over *Griffiths, et al.* (Methods in Molecular Biology (1997) 75:59-76). Advisory Action at page 2. Applicant contends that this rejection is improper because *Griffiths* does not describe, either expressly or inherently, Applicant's invention as set forth in the claims.

According to M.P.E.P. § 2131, "(A) claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Applicant's claim 1, as amended, now recites a "method comprising: a) culturing cells to form a preproduction batch, b) dividing the cells of the preproduction batch into at least two separate batches, c) employing at least one of the separate batches for the preparation of at least one production batch for the production of at least one biological, d) employing at least another of the separate batches as a seed for the preparation of at least one subsequent preproduction batch...."

Griffiths describes methods for growing suspension cultures (item 3.1), growing anchorage-dependent cultures (item 3.2), and growing porous carrier cultures (item 3.3). At no place does *Griffiths* describe dividing cells into separate batches and employing the separate batches for the production of at least one production batch and at least one preproduction batch. Accordingly, Applicant respectfully asserts that *Griffiths* fails to describe, either expressly or inherently, Applicant's invention as set forth in the claims, and requests that this rejection be withdrawn.

Applicant notes that the Examiner has requested evidence showing the "significance of the 50% splitting," both in the Advisory Action and in the telephone conversation with Applicant's representative held on June 24, 2002. See Advisory Action at page 2. Applicant respectfully points out that the present claims do not require any 50% splitting. Accordingly, evidence showing the significance of a 50% splitting should not be required.

III. Rejection under 35 U.S.C. § 103(a)

Claims 1-2 and 7-22 were rejected under 35 U.S.C. § 103(a) over *Griffiths* in light of *Pollard* (Methods in Molecular Biology (1997) 75:1-11). Advisory Action at page 2. Applicant contends that this rejection is improper because the combination of these references does not teach or suggest the claimed invention.

A rejection under 35 U.S.C. § 103(a) requires, among other things, that the alleged prior art references, when combined, "must teach or suggest all the claim limitations." M.P.E.P. § 2143.

Applicant's claim 1, as amended, now recites a "method comprising: a) culturing cells to form a preproduction batch, b) dividing the cells of the preproduction batch into at least two separate batches, c) employing at least one of the separate batches for the preparation of at least one production batch for the production of at least one biological, d) employing at least another of the separate batches as a seed for the preparation of at least one subsequent preproduction batch...."

As discussed above, *Griffiths* fails to describe dividing cells into separate batches and employing the separate batches for at least one production batch and at least one

preproduction batch. *Pollard* does not cure this failure. *Pollard* teaches methods for establishing and maintaining cell cultures and methods for freezing the cells (items 3.1-3.3). *Pollard* does not, however, teach or suggest dividing cells into separate batches and employing the separate batches for at least one production batch and at least one preproduction batch. Thus, the applied references, when combined, fail to teach or suggest all the limitations set forth in Claim 1. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Applicant respectfully requests entry of these amendments, reconsideration of this application, and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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